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| EXAMINER |
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WILLIAMS, CATHERINE SERKE

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| ART UNIT | PAPER NUMBER |
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3763

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08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,021

Applicant(s)

FEELEY ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/14/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) 6,9-11,13 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4,12 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyeoka et al (USPN 3,595,230) in view of Utterberg et al (USPubN 2003/0175323) in further view of Hall et al (USPubN 2003/0212373).

Suyeoka discloses an intervention device rod (6); a hub (10 with an extension arm (8) and a delivery tube (2). The delivery tube has a longitudinal partition with a hub opening (see figure 3).

Suyeoka meets the claim limitations as described above but fails to include the rod being an antimicrobial bearing device. However, Utterberg discloses a catheter/rod that includes iodine. The iodinated catheter/rod is designed with the antimicrobial treatment in order to reduce problems with infection. See paragraph 0002.

At the time of the invention, it would have been obvious to incorporate the teaching of a antimicrobial iodine into the invention of Suyeoka. Both devices are analogous in the art of percutaneous administration into a patient; therefore, a combination is proper. Additionally, the motivation is provided in that Utterberg teaches an enhanced design for reduced infection in a patient which is also an objective of Suyeoka thereby resulting in enhanced sterility.

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Suyeoka meets the claim limitations as described above but fails to include the longitudinal partition being perforated.

However, Hall teaches a shield with a perforated longitudinal partition. See figure 1A #30.

At the time of the invention it would have been obvious to incorporate the perforations of Hall into the invention of Suyeoka. The motivation would have been in order to provide the shield of Suyeoka with enhanced sterility which is disclosed as an objective of the invention. Additionally, Applicant has failed to establish that the perforated slit provides an advantage, is used for a particular purpose or solves a stated problem. Furthermore, one would expect a continuous slit or a perforated slit to perform equally well considering that either slit would enable the rod to be advanced toward a patient and detached from the delivery tube.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyeoka et al (USPN 3,595,230) in view of Hochman (USPN 6,726,658).

Suyeoka meets the claim limitations as described above but fails to disclose that the extension arm and the hub have a tapered connection point that enables removal of the extension arm.

Hochman discloses an intervention rod (94), a hub (92), and a delivery tube (12) where longitudinal movement of the hub by a connected extension arm (100,50,80,82 and 84) and finally a clinician (see 52-53) ejects the intervention rod from the delivery tube (12) and detaches the rod from the delivery tube. See figures 1-4. The tube has a continuous slit longitudinal partition (24) and hub opening (32) which allows access to the hub via the exposed portion of

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extension arm (100). The arm and hub have a tapered connection point (84,92) that enables removal. See figures 3-4.

At the time of the invention it would have been obvious to incorporate the tapered removal point into the invention of Suyeoka. Both devices are analogous in the art; therefore, a combination is proper. Additionally, the motivation for the incorporation would have been known by one skilled in the art in that removal of the extension arm would allow the hub to be positioned on the patient skin without any rotation prior to positioning.

Claims 14-16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyeoka in view of Utterberg in view of Hall in further view of Chang et al (USPN 5,419,766). Suyeoka in view of Utterberg in view of Hall meets the claim limitations as described above but fails to include the delivery tube being made from a polyester.

However, Chang discloses polyester sheaths. The material is used for its hydrophobic property to prevent moisture from traveling through the sheath. See 7:35-62.

At the time of the invention, it would have been obvious to incorporate the material, i.e. polyester, as taught by Chang to make the delivery tube of Suyeoka in view of Utterberg in view of Hall. The devices are analogous in the art of percutaneous administration; therefore, a combination is proper. Additionally, the motivation is provided by Chang in that the material prevents moisture from traveling through the sheath. One skilled in the art would reasonably conclude that by preventing the transmission of moisture through the tube one would enhance the sterility of the device prior to use thereby enhancing the safety to the patient.

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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyeoka et al (USPN 3,595,230).

Suyeoka meets the claim limitations as described above but fails to disclose a valve coupled to an open end of the delivery tube.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate a valve, such as a hemostatic valve into the invention of Suyeoka. Hemostatic valves are well known in the medical device arts and are provided in order to prevent fluid leakage and maintain sterility. One skilled in the art would reasonably include a hemostatic valve in order to maintain sterility of the internal components which is an objective of Suyeoka.

Response to Arguments

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation for the combinations is found in the knowledge generally available to one of ordinary skill in the art. Additionally, applicant has failed to present that the perforations provide an advantage, are used for a particular purpose or solve a problem. Therefore, one would expect the perforations or a slot to perform equally well.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Catherine S. Williams/
Catherine S. Williams
Primary Examiner, Art Unit 3763
July 24, 2007